

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Offic

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Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | | | ATTORNEY DOCKET NO. | |
|---|-------------|----------------------|----------|-----------------------|---------------------|---|
| 19/402,737 | 10/08/99 | NEUSER | | D | BAYER10197 | |
| _ | | | | | EXAMINER | |
| HM12/0410 ' NORRIS, MCLAUGHLIN & MARCUS, P.A. ATTN: CAARMELLA A. O'GORMAN | | | | GEORGE, | , K | |
| | | | ART UNIT | PAPER N | UMBER | |
| 60 WHITE PL TH FLOOR | AINS ROAD | | | 1616 | | Ç |
| ARRYTOWN NY 10591-5144 | | | | DATE MAILED: 04/10/00 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | Application No. | Applicant(s) | | | | | | |
|--|--|---|--|--|--|--|--|--|
| | 09/402,737 | NEUSER ET AL. | | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | | |
| | Konata M. George | 1616 | | | | | | |
| The MAILING DATE of this communication appe Period for Reply | ars on the cover sheet with the co | rrespondence address | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. | ' IS SET TO EXPIRE 3 MONTH(| S) FROM | | | | | | |
| Extensions of time may be available under the provisions of 37 after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days be considered timely. If NO period for reply is specified above, the maximum statutory communication. Failure to reply within the set or extended period for reply will, be Status | cation. s, a reply within the statutory minimum of period will apply and will expire SIX (6) N | thirty (30) days will | | | | | | |
| 1) Responsive to communication(s) filed on | · | | | | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ Thi | s action is non-final. | | | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | | |
| Disposition of Claims | | | | | | | | |
| 4)⊠ Claim(s) <u>1-4</u> is/are pending in the application. | | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | | |
| 6)⊠ Claim(s) <u>1-4</u> is/are rejected. | | | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | | | |
| 8) Claims are subject to restriction and/or election requirement. | | | | | | | | |
| Application Papers | | | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | | |
| 10) The drawing(s) filed on is/are objected to by the Examiner. | | | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved. | | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | | |
| Priority under 35 U.S.C. § 119 | • | | | | | | | |
| 13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). | | | | | | | | |
| a)⊠ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been: | | | | | | | | |
| 1.⊠ received. | | | | | | | | |
| 2. received in Application No. (Series Code / Serial Number) | | | | | | | | |
| 3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| 14) Acknowledgement is made of a claim for dome | stic priority under 35 U.S.C. & 11 | 9(e). | | | | | | |
| Attachment(s) | | · | | | | | | |
| 14) Notice of References Cited (PTO-892) 15) Notice of Draftsperson's Patent Drawing Review (PTO-948) 16) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 | 18) Notice of Informal | y (PTO-413) Paper No(s) Patent Application (PTO-152) | | | | | | |

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DETAILED ACTION

Claims 1-4 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
- 1. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Bourke et al. (U.S. Patent No. 5,637,320).

Bourke et al. ('320) teaches a formulation for oral administration in a multiparticle form, where the first portion is designed to release the drug at a rate as to maintain therapeutically effective blood levels (i.e. sustained release) and a second portion is formulated so as to release the drug promptly following administration to obtain a relatively immediate therapeutic response (i.e. rapid release) (col. 1, lines 60-67 and col. 2, lines 1-2). The reference teaches the drug as an analgesic i.e. naproxen (col. 1, lines 17-19). The reference teaches formulations of the invention maintaining a therapeutic effect over a 24hr period with peak levels between 2-16 hours (col. 3, lines 3-7). The reference teaches the formulations further containing lubricants and polymeric materials (col. 3, lines 23, 28-30).

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Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Konata M. George, whose telephone number is

(703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday

to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for

the organization where this application or proceeding is assigned are (703) 308-4556 for

regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is

(703) 308-1235.

KMG

JOSE'G. DEES SUPERVISORY PATENT EXAMINER

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